REMARKS

This Amendment After Final Rejection is being submitted in response to the Official Action mailed in this application on April 11, 2007. A Notice of Appeal accompanies this Amendment. Entry of this Amendment, and reconsideration of this application, are respectfully requested.

First, with respect to the specification, Applicants noted in their last response that the "guidelines illustrate the *preferred* layout" (emphasis added). Since no particular arrangement is *required*, Applicants believe that, contrary to the comment in the action, they have argued against the objection. Nevertheless, even though it is not required, in an effort to satisfy the Examiner, Applicants have amended the specification to add headings. Accordingly, applicants believe the objection has been obviated.

Next, claims 25-28 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Specifically, it was asserted that the expression "when measured after 5 hours" is new matter. While Applicants disagree, in order to advance the prosecution of the application, the claims have been amended to require a concentration of less than 1.5 ppm. Literal support for this amendment can be found in paragraph 12 of the instant application as published.

Finally, claims 25-28 were rejected under 35 U.S.C. 103(a) as being unpatentable over any of WO 01/024839, WO 02/43743, WO 02/078755, an article by Nathan, et al., EP 361722, WO 00/09173, US 6592888 or US 2002/0172709. Applicants traverse this rejection.

The present invention concerns the prevention of skin staining of a wound treated with a silver containing wound dressing. The problem with treating wounds with silver is that elemental silver or silver compounds tend to precipitate out of the wound fluid and, consequently, when ionic silver is delivered to the wound, silver and silver compounds precipitate on the wound and skin turning them black. Most wound dressings are designed to release silver to the wound rapidly to treat or prevent infection. That same strategy causes staining. The challenge, then, is to deliver silver to the wound at a level that is effective to treat or prevent infection but which is at or

below the solubility limit of silver or silver compounds in water so that there are no deposits on the wound and skin.

Certain features of the present claims are that the release of ionic silver is less than 1.5 ppm and that the release is controlled. 1 ppm is the solubility limit for silver chloride in water. As the level raises much above 1 ppm, silver chloride will deposit on the wound and skin. That certain dressings do prevent skin staining can be seen in Figures 1 and 2.

None of the cited art appears to be concerned with *skin* staining at all and none suggests that it may be an advantage of the materials disclosed therein. WO'173 appears to be concerned with preventing discoloration of the dressing during storage. This is not the same as preventing discoloration of the skin of the patient during use.

The rejection focuses on the amount of silver present in the dressing. However, it is the controlled release as required by the claims that gives the amount that is important to achieving the lack of skin staining.

It is argued in the action that all the cited documents disclose the release of silver into the wound from wound dressings made from the same polymer materials as claimed by Applicants, that all the documents teach the same amount of silver in the wound dressings, and it would therefore be expected that these dressings will release the same amount of silver into the wound. This is abundantly not true as can be seen from the examples. It is apparent from the results in, *e.g.*, Example 1 and Example 4, that not all dressings give a controlled release of silver ions into water. Compare, for instance, the result for Aquacel Ag at 98 hours with that for Acticoat Moisture Control at 98 hours in Example 1. The ppm of silver in solution for Aquacel Ag is 0.6 or 0.4 while that for Acticoat Moisture Control is 5.3. As can be seen from the table in Example 1, Aquacel Ag contains 1.2% silver on a dry weight basis while Acticoat Moisture Control contains 2%. Acticoat Moisture Control is a foam product which is coated with metallic silver. While it is true that Acticoat Moisture Control starts with approximately twice the weight of silver on a dry weight basis, the release of silver from Acticoat Moisture Control is approximately 8 times that for Aquacel Ag. Critically, though, there is no realization in the prior art products that this level of silver release will lead to deposition of silver and silver compounds onto the wound and skin leading to skin staining.

Applicants' invention is centered on the realization that it is control over the release of silver, and more importantly the maintaining of the release generally below the solubility limit of silver compounds, that maintains the silver ions in solution and prevents the deposition of silver or silver compounds. None of the cited documents recognizes this or disclose it. Applicants have found a way to make an effective dressing which does not stain the patient and therefore brings the advantages of using silver without the disadvantages.

The action goes on to mention Example 4. First, it is stated in the action that Acticoat is the wound dressing of WO '743. It is not, and applicants have not said that it is. It is alleged that the comparison of Acticoat with the dressings of the invention is unfair because the comparison does not show the concentration of silver ions in the dressing of the present invention nor which embodiment of '743 is used in the comparative data. The method of '743 is used to prepare the samples of Aquacel Ag as disclosed at paragraph 19. The table in Example 1 shows the amount of silver on a dry weight basis for all the dressings to which the invention is compared. Example 4 compares Acticoat Burn to a dressing according to the invention (Aquacel Ag). The amount of silver on a dry weight basis for Acticoat Burn is 10.3%, while for Aquacel Ag it is 1.2% (from Example 1). From Example 4, the ppm of silver in solution for Aquacel Ag is 0.8 at 5 hours while for Acticoat Burn it is 35.1. While Aquacel Ag contains about ten times less silver on a dry weight basis than Acticoat Burn, the ppm of silver ions in water for Aquacel Ag is 43 times less than the ppm in water for Acticoat Burn at 5 hours. The comparison is a fair one because the amounts of silver in the dressings are disclosed. As is shown in Figs. 1 and 2, there is significant skin staining with the Acticoat dressings whereas none is seen with the dressings according to the invention.

For all these reasons at least, Applicants request that this rejection be withdrawn.

In view of the foregoing, entry of this amendment, reconsideration of this application, withdrawal of the rejections and objection, and allowance of the application with claims 25-28, are all respectfully requested.

Respectfully submitted,

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